



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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October 29, 2001

Kenneth L. Dretchen, Ph.D.
Director, Office of Regulatory Affairs
Georgetown University
3900 Reservoir Road, N.W.
NW103 Medical-Dental Building
Washington, D.C. 20007

**RE: Human Research Subject Protections Under Multiple Project Assurance (MPA)
M-1255**

Research Project: Functional MRI Studies of the Pathophysiology of Dyslexia
IRB Project Number: 250-96
Principal Investigator: Guinevere Frauke Eden, Ph.D.

Dear Dr. Dretchen:

The Office for Human Research Protections (OHRP) has reviewed your report of September 28, 2001, regarding the above referenced research project conducted by Georgetown University (GU).

Based on its review of your report, OHRP has determined that the corrective actions taken by GU appropriately address the issues raised.

As a result, there should be no need for further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified which might alter this determination.

OHRP appreciates your institution's continued commitment to the protection of human research subjects. Do not hesitate to contact me if you have any questions regarding this matter.

Sincerely,

Kristina C. Borrer, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Mrs. Elizabeth Crigler, Executive Officer, IRB, GU
Dr. Willard A. Barnes, Chair, IRB, GU
Dr. Guinevere F. Eden, GU
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA
Dr. Greg Koski, OHRP
Dr. Melody H. Lin, OHRP
Mr. George Gasparis, OHRP
Dr. Jeffrey M. Cohen, OHRP
Mr. Barry Bowman, OHRP